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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,434	10/25/2001	Rajendra Singh	SURR.74	2960

25871 7590 03/04/2005

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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/047,434	Applicant(s) SINGH ET AL.	
	Examiner Mary (Molly) E. Ceperley	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 8-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/03/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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1) The references cited on form PTO-1449 submitted on December 03, 2004 have not been considered for the reason that they have not been presented in a form which is readable by the examiner (see PAIR for ARTIFACT SHEET of December 03, 2004). It is further noted that both references AG and AH appear to reference entire conference proceedings. The citations do not adequately reference the sponsoring organizations, conference dates, conference locations and volume and page numbers of the articles.

2) Claims 4-6 and 8-11 are currently pending and under active prosecution.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

5) Claims 4-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) It is unclear what is meant to be encompassed by the term "protein component" in claim 8. Although the term would be conventionally interpreted to mean a protein *per se*, claims 4-6 indicate that a protein subunit, an amino acid, is also intended by this term. It is unclear what moieties are required for the "protein component" and the specification fails to define a "protein component".

b) Claims 4-6 and 8-11 are again rejected for the reason set forth in paragraph **5)c)** of the June 25, 2004 Office action. Applicant's arguments filed December 27, 2004, Remarks, page

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10, paragraph c), have been fully considered but they are not persuasive. First, the use of the term "a protein component" to replace the term "certain protein functional groups" does not provide further clarification of the exact composition of the reagents (see paragraph *a*) directly above). Second, applicants have not addressed the problem that the reagent is inadequately defined for the reason that the only requirement for the structure of the reagent is that it contain "an amino acid reactive moiety" and that it be "differently labeled"; these two requirements are insufficient to chemically, structurally and functionally define the claimed reagents.

c) It is unclear what is meant by the term "derivatized amino acid". The chemical nature of the derivatization is unclear. The description of page 15, lines 7-16 of the specification refers to one specific derivatization of a lysine moiety but does not generically describe what is meant to be encompassed by the term "derivatized".

d) It is unclear what portion of the "protein component" the "amino acid reactive moiety" reacts with. It is necessary to specify which functional group of the "protein component" is reacted with the "amino acid moiety" for the reason that this functionality determines what is meant to be included by the term "amino acid reactive moiety". It is noted that the intended method of use limitations of claims 10 and 11 (i.e. "react with") are not limitations on the product *per se*.

6) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7) Claims 4-6 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the specification of the terms "derivatized amino acid" and "protein component".

8) Claims 4-6 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Aebersold et al (US 6,670,194) for the reasons stated in paragraph **7)** of the June 25, 2004 Office action.

Applicants argue that the mere suggestion in Aebersold et al that the linker portion of the Aebersold et al reagent can be substituted does not teach or imply that the substitution results in reagents that are differently labeled with one or more non-isotopic chemical substituents. This argument is unpersuasive however, for the reason that what is being claimed is a composition which is the same as the composition of Aebersold et al. The fact that each of the instantly claimed reagents of the composition may be characterized as containing "one or more non-isotopic chemical substituents" while the reagent composition of Aebersold et al is characterized as containing optionally substituted alkylene groups is irrelevant for the reason that the Aebersold et al patent and the instant claims define the same compounds. The Aebersold et al reagents are inclusive of the reagents of the instant claims wherein each reagent is required to contain only "an amino acid reactive moiety" and a moiety which is "differently labeled with one or more non-isotopic chemical substituents".

9) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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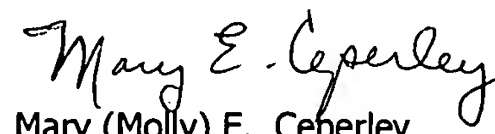
date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 03, 2005


Mary (Molly) E. Ceperley
Primary Examiner
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